# The National Organic Program
# Biotech Test Methods and Protocols for Use in Organic Compliance
# A Report to the Office of the Inspector General
# February 2013

**Contents**



## Executive Summary

In February 2012, the Office of the Inspector General (OIG) issued Audit Report 01601-0001-Te, Agricultural Marketing Service (AMS), National Organic Program – Organic Milk. The OIG initiated the audit to determine whether milk marketed as organic meets the USDA organic regulations. In its report, the OIG recommended that the National Organic Program (NOP) conduct a study of testing methods that may be used to detect the presence of genetically modified (GM) materials in organic livestock feed. Based on the findings of the study, AMS would determine if it would need to publish guidance on GM testing for its certifying agents.[1] This report responds to that recommendation.

Genetic modification is an excluded method under the USDA organic regulations. While GM material may be present due to drift of GM pollen or other uncontrolled sources, detection of GM materials in organic livestock feed would indicate a possible violation of those regulations.

Two testing methods are most commonly used by the industry to detect the presence of GM material. Polymerase chain reaction (PCR) is a DNA-based test conducted in the laboratory. PCR is a highly sensitive test that can detect multiple GM events with a single test. However, it is relatively expensive and may take hours or days to provide results. A second test method, enzyme-linked immunosorbent assay (ELISA) is a less expensive test that identifies GM events by detecting a specific protein produced by the GM plant. It is relatively quick and simple to use and is much less sensitive compared with PCR. Trained personnel can conduct testing in the field and observe results in a matter of minutes. Generally, the protein must be intact in order for the ELISA method to provide reliable results.

As materials used for organic livestock feed move along the production and handling continuum, there are several points where organic feedstuffs may come in contact with GM agricultural products. The NOP study identified appropriate GM testing methods for each of these potential points of contact.

There are significant USDA resources available to the industry regarding sampling and testing for GM material presence in organic products. The Grain Inspection Packers and Stockyards Administration (GIPSA) assists the industry with sampling protocols, manages a proficiency testing program, and validates testing methods used to detect GM materials in grains and oilseeds. The AMS Science and Technology Programs' National Science Laboratory provides testing services to detect GM materials.

The USDA organic regulations are clear that using GM material is prohibited in organic production and handling. There are procedures for certifiers and official guidance already provided by AMS and other USDA agencies regarding the testing of organic agricultural products for the presence of GM material. Further guidance beyond what has already been provided by the USDA would not address any specific needs at this time.

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**Introduction**

The United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS) operates the National Organic Program (NOP) to develop, implement, and administer national

standards governing the marketing of organic agricultural products and to assure consumers that such products meet consistent standards.

In February 2012, the Office of the Inspector General (OIG) released its Audit Report 01601-0001- Te, Agricultural Marketing Service, National Organic Program – Organic Milk.[1] The OIG made four recommendations, one of which was that NOP should conduct an analysis of genetically modified (GM) detection methods and protocols. Based on the analysis results, NOP should determine whether to develop and issue guidance for certifying agents on the utilization of GM detection methods to identify potential violations of the USDA organic regulations.

AMS agreed to conduct an analysis of GM detection methods and protocols as a necessary prerequisite in the development of any potential draft guidance related to GM testing. The analysis examines the reliability and utility of various testing protocols with respect to determining the likelihood that GM was intentionally used (violation of the standard) or was unavoidably present (not a violation), which is an essential distinction for enforcement purposes. AMS agreed to complete the analysis by February 13, 2013. The OIG accepted AMS's management decision on the recommendation. This report is in response to the OIG recommendation.

**Preparing the report**

To prepare this report, NOP staff reviewed research and consulted with experts in statistical analysis and biotechnology from various USDA agencies and AMS staff with specific expertise in grain production, harvesting, and handling. We also consulted with industry experts in the fields of biotechnology, manufacturing, distribution, and persons currently active in biotech coexistence policy development. Most of the industry experts interviewed for this report spoke on conditions of anonymity. Persons interviewed included representatives of grain handlers, processors, testing services, farming cooperatives, scientists in the field of genetic material detection, and representatives of companies that produce GM rapid test kits.

The purpose of this paper is to discuss methods used to sample and test organic agricultural products for the presence of GM material and to determine whether GM testing guidance would

be valuable to certifying agents in maintaining the integrity of organic products. In this paper, we will:

- Examine existing AMS regulations, guidance, polices, and resources regarding testing of organic livestock feed for the presence of GM materials.
- Provide an analysis of GM detection methods and protocols used in the testing of organic livestock feed.
- Identify points in the production and handling continuum where there is a possibility for GM material to come into contact or become commingled with organic livestock feed stuffs.
- Discuss where testing may be best utilized to determine the presence and source of GM material.
- Analyze the information provided and determine if AMS needs to provide additional guidance on GM testing for certifying agents to ensure that organic livestock feed stuffs have been produced in compliance with the USDA organic regulations.

**Background**

The first GM livestock feed crops became available for use by farmers and ranchers in 1995 when the Animal and Plant Health Inspection Service (APHIS) deregulated 20 GM varieties, including corn, soybeans, and cotton.[2] Corn, soybeans and cotton seed meal are common crops used for livestock feed in the U.S. According to data from the Economic Research Service, 88% of corn and 93% of soybeans grown in the U.S. had at least one genetically modified trait.[3] Other GM crops used for livestock feed include GM alfalfa which was deregulated in 2011.[4]

Careful production practices such as cleaning equipment, timing the planting of crops, and maintaining adequate buffer zones can minimize the occurrence of GM material in organic crops. However, according to anecdotal reports, an abundance of GM pollen in some agricultural production areas makes it possible for an organic farmer to produce a crop in compliance with the USDA organic regulations and still detect some level of GM material in the harvested organic crop. Despite sound organic management practices, containers of organic grain sometimes test positive for GM material upon arrival at market. Organic grains and oil seeds are sometimes rejected for contractual reasons when testing indicates the presence of GM material

upon arrival at an elevator or other receiving market. When this occurs, organic producers may have to unexpectedly sell the grain as non-organic at a much lower price. According to NOP Policy Memo 11-13, the presence of genetically modified material in the organic crop is not a violation as long as an operation has taken reasonable steps to avoid contact with the products of excluded methods. The low level presence of GM material is the topic of ongoing discussions for two Federal advisory committees, the National Organic Standards Board and the USDA Advisory Committee on Biotechnology and 21st Century Agriculture.

**USDA Organic Regulatory Requirements**

The USDA organic regulations prohibit the use of "excluded methods" to produce products, including organic livestock feed, that are intended to be sold, labeled, or represented as "100% organic," "organic," or "made with organic (specified ingredients)." [5] The USDA organic regulations define excluded methods as "a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture." [6]

NOP certified organic operations must have procedures in place that preclude the use of GM seed for the production of organic crops. NOP certified organic handlers must have procedures in place that prevent the commingling of organic crops with non-organic GM crops. NOP accredited certifying agents must ensure these procedures are documented in a written organic production or handling plan. Onsite inspections by the certifying agent or their representative must verify that written procedures are fully implemented and effective to avoid contact with GM crops or products.

On November 9, 2012, the NOP published revised regulations on residue testing of organic products. Effective January 1, 2013, certifying agents must select samples from at least 5% of

their certified operations for testing for the presence of residues of prohibited substances. This may include testing for GM material. AMS officials, State organic program officials, or the operation's NOP-accredited certifying agent may require additional pre-harvest or post-harvest testing of any agricultural input used or agricultural product when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. If testing is conducted, such testing must be conducted at the State organic program or certifier's own expense. Results of those tests must be made available to the AMS Administrator. All organic products, including organic livestock feed, must be made accessible for testing by NOP officials or the certifying agent of the organic operation.[7] To date, the NOP has not received any results of testing conducted by certifying agents to detect the presence of GM material.

Persons who violate the USDA organic regulations by using excluded methods to produce an organic crop are subject to suspension or revocation of their organic certification. Further, persons who sell such a crop as organic may be subject to a civil penalty of not more than $11,000 per violation.[8]

**Existing NOP Guidance Related to Presence of and Testing for Excluded Methods**

The USDA organic regulations do not specify and the NOP has not issued any guidance on the amount of GM material that may be present in an organic crop and still be labeled as organic. The Preamble to the NOP Final Rule states: "As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of the organic operation or its organic products." [9]

In a September 2004 letter to the National Association of State Departments of Agriculture, Agriculture Undersecretary Bill Hawks stated that the presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the NOP regulations. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods, the unintentional presence of the products of excluded methods will not affect the status of the organic operation. Even when an

approved buffer zone fails to provide the protection that both the operator and the certifying agent reasonably expected, the certifier must not "retroactively" punish the producer by an enforcement action or "de-certify" the organic crop. The appropriate action to take in this case is to re-evaluate the buffer zone and other preventive measures in the plan to ensure improved integrity and performance in the future. As to the status of the commodity, USDA's position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship.

The September 2004 letter further emphasized the importance of the organic systems plan stating that "the certifying agent must not approve a plan that does not provide evidence of sound measures taken to ensure the integrity of the organic crop operation, including buffer zones and other steps to prevent commingling with unapproved non-organic materials and conventional crops. If a producer does not adhere to such preventive measures, the certifying agent is expected to denote such failure as a noncompliance and take appropriate measures toward correction by the producer." [10]

In an April 15, 2011 policy memorandum, the NOP reiterated this policy and further clarified that "the inadvertent presence of GMOs in organic seeds does not constitute a use [of an excluded method] because there was no intent on the part of the certified operation to use excluded methods. The presence of detectable GMO residues alone in an organic seed does not constitute a violation of the NOP regulations."[11]

If the certifier determines that the source of low levels of GM material in a product labeled as organic is from commingling or coming in contact with non-organic products, the certifier may issue a notice of noncompliance for violations of the USDA organic regulations at section 205.272 Commingling and contact with prohibited substances prevention practice standard.

**Other Related NOP Provisions**

In addition to regulations and policy memoranda, the NOP has issued procedural instructions to certifying agents for conducting testing for residues in organic crops. On November 8, 2012, the NOP issued Instruction 2610, Sampling Procedures for Residue Testing. This instruction outlines the sampling procedures recommended by the NOP for parties conducting residue testing of organically produced agricultural products.[12] Concurrently, NOP issued NOP Instruction 2611,

Laboratory Selection Criteria for Pesticide Residue Testing. This document outlines the laboratory criteria recommended by the NOP for parties conducting pesticide residue analysis of organic products.[13] Also on June 13, 2011, NOP issued draft guidance on responding to results from pesticide residue testing.[14] This document provides the framework for responding to positive test results and will be finalized in the near future.

In January 2012, NOP conducted training on GM presence in organic products at the annual certifier training. In January 2013, NOP conducted training on responding to positive residues (including GM presence) at the annual certifier training. These training slides are available to all certifiers on the NOP website.

**USDA Agency Roles**

Various agencies within USDA play different roles related to the use and detection of GM in organic livestock feeds, including the issuance of technical guidance useful to NOP and accredited certification agents. Responsibilities include:

- Examining the safety of a GM material and releasing it for use in agriculture.
- Sampling loads or containers of agricultural products for further testing.
- Evaluating the accuracy of GM material test kits.
- Assessing the competence of testing laboratories through voluntary proficiency testing.
- Testing samples of grain and other products for GM material.

**Animal and Plant Health Inspection Service**

The USDA Animal and Plant Health Inspection Service (APHIS) is the USDA agency responsible for the regulation of plant varieties that have been genetically engineered. The Biotechnology Regulatory Services (BRS), a program within APHIS, implements APHIS regulations for certain genetically engineered organisms that may pose a risk to plant health. APHIS coordinates these responsibilities along with other designated federal agencies as part of the Federal Coordinated Framework for the Regulations of Biotechnology. Depending upon the specific technology, other federal agencies such as the Environmental Protection Agency or the U.S. Food and Drug Administration may also be involved in the review and approval process.

APHIS regulates products to control their use in agricultural production. When a developer of a genetically engineered crop has collected enough evidence that the GM organism poses no more of a plant pest risk than an equivalent non-GM organism, the developer may petition APHIS to determine non-regulated status for the GM organism. If the petition is approved by APHIS, the GM organism may then be introduced into the United States without any further APHIS regulatory oversight.[15] Information regarding the deregulated status of a GM material is published in the Federal Register.

**Grain Inspection, Packers & Stockyards Administration**

The USDA Grain Inspection Packers and Stockyards Administration (GIPSA) provides a range of services to support the industry as described below.

Rapid Test Kit Evaluation Program**.** GIPSA has a voluntary program to verify the performance of rapid test kits used by industry to detect the presence GM material. GIPSA's Rapid Test Kit Evaluation Program ensures that test kits used by grain elevators and other buyers and sellers of grain products can reliably detect specific GM proteins at the levels declared by the manufacturers.

To participate in the Test Kit Evaluation Program, the test kit manufacturer submits a data package supporting their claims, such as the GM events detected and levels of detection. GIPSA staff then reviews the data submitted by the manufacturer. If the data package is complete and the claims of the rapid test are supported by the data, GIPSA conducts an in-house performance test. If the manufacturer's claims are verified by GIPSA's in-house performance test, the manufacturer receives a GIPSA Certificate of Performance that is valid for 3 years from the date of issue. Certificates expire after 3 years if not renewed. There are currently 8 rapid test kits from 2 manufacturers that are listed as verified by GIPSA.[16]

Proficiency Program**.** In 2002, GIPSA began offering a Proficiency Program to organizations testing for biotechnology-derived grains and oilseeds. This program was designed to improve the overall performance of and confidence in testing for biotechnology-derived grains and oilseeds. The program evaluates each participating laboratory's ability to detect and/or quantify GM material in corn and/or soybeans and documents laboratories' continuing performance. Participating laboratories receive sets of samples for both qualitative (detection) and quantitative

(level measurement) analysis. The participating laboratories submit their results to GIPSA and the Agency then generates a publicly-available report of the results of the evaluations.

Participation in the program is voluntary and the program is structured to allow individual laboratories to self-evaluate their performance. Participants may remain anonymous or allow their names to be published along with the results of the testing. Some laboratories participate in this type of group testing program, referred to as "ring testing," and allow their names to be published to meet the requirements for other accreditation programs.

The Proficiency Program distributes samples twice each year, in April and October. In October 2012, 77 organizations submitted requests to participate in the program.[17] The results of the testing are published on the GIPSA internet website.

Sampling Guidelines. Sampling is the single largest source of error in the analysis of grains.[18] GIPSA provides plain-language sampling guidelines for use in the grain handling industry. These guidelines are posted on the internet and are available for use at no cost to the industry. GIPSA also works with members of industry or government to develop sampling protocols to meet specific user requirements.[19]

**AMS – National Science Laboratory**

The AMS National Science Laboratory located in Gastonia, NC, is a full-service laboratory testing facility assisting the public, including producers, handlers, certifying agents, and others with a variety of services. User-fee services are provided based on an hourly rate, including the detection of GM materials in food, plants, and seeds. Testing for GM material is accredited under the International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17025:2005 – General requirements for the competence of testing and calibration laboratories. The National Science Laboratory provides both qualitative and quantitative tests, including, but not limited to, PCR and ELISA tests.[20]

**Testing Services Available Through the Private Sector**

By the time newly deregulated GM plants are introduced for use in agriculture, testing companies may have already begun to develop products or services to detect the presence (or absence) of the new GM material in agricultural products. Samples of the GM material are

obtained through proprietary agreements with the life science companies who developed the GM event. There are numerous private sector companies providing a variety of services related to GM material testing. Services range from the design and supply of test kits to actual testing services. Some service providers offer GM testing as a part of customized services to support internal quality management systems and contractual agreements.

**Sampling**

Each time an organic product is handled there is the opportunity for the introduction of GM material. If the purpose of testing is to identify the source of GM material, samples drawn early in the process prior to commingling with feed from other sources would be more likely to identify the source of GM material. If testing is to provide assurances to consumers that a particular finished product does not contain GM material, sampling closer to the final product provides higher levels of assurance for that purpose. Contractual compliance at any point of the production/distribution chain may be verified by sampling each time the product changes custody.

Designating a lot. A lot may be designated as a field, a portion of a field, or truckload, etc., depending on the purpose for the sampling. Designating a portion of a field, such as the area bordering a field containing a GM crop, is sometimes useful in helping identify or rule out sources of GM material. Sampling programs should consider possible differences in the presence of GM material at different locations in the products being sampled. Variation within the lot may be related to the cause of the GM presence. For example, if GM presence is due to drift from a nearby field, there could be relatively high presence in the areas immediately adjacent to the field containing a GM crop but zero presence further away from the GM crop.

Greater measurement variability in a sampled lot indicates the need for a larger number of samples to be tested, to obtain a more accurate assessment of the level of GM content in a load. Sometimes it is advisable to separate the lot into sub lots to provide an accurate assessment of the level of GM material in a sampled population.

Confidence level. Sample confidence levels are affected by the number and size of samples taken and the variation within the population. Sample confidence is expressed as a percentage of time that the test will yield an accurate result. For example, a test confidence level of 95% would

mean that a testing method has been designed so that a quantity of livestock feed containing a particular target level of GM material would test positive for GM material 95% of the time.

Sampling selection method. Sampling procedures will describe where and how the samples will physically be extracted. Samples may be drawn from static lots consisting of truck loads, piles or bins of grain. In other situations, samples may be drawn from moving streams of grain such as conveyor belts. The method selected should ensure the sample represents the entire lot or sub lot.

Sample size. Sample accuracy may be improved by increasing sample size, by taking a larger number of samples, or taking several samples and combining them into a composite sample. Large samples may sometimes need to be divided into sub-samples for testing in order to provide reliable results, depending on the sensitivity of the test. For a given lot, the size of the sample to be taken depends on a number of factors. Large lots with a high degree of variability require larger sample sizes to achieve a required level of confidence in the results. Smaller lots or lots with a lesser degree of variation within the lot may be accurately sampled with fewer samples.

**Sampling Guidance from USDA**

The Federal Grain Inspection Service has established guidelines for practical application of sampling for the detection of GM grains. The chart below shows the size of samples to be taken to attain a 99%, 95%, or 90% confidence level for testing lots containing from .05 to .50% GM material. As shown by the chart, as the presence of GM material in the lot increases, the size of samples needed to detect the presence for a given confidence interval decreases. Similarly, as the need for confidence in the determination decreases from 99% down to 95% and 90%, the sample size decreases. Some persons requesting service may have even more stringent requirements. In order to ensure that samples are large enough to accommodate most users' needs, FGIS has established their sample size as 5 Kg. The sample can be reduced at the lab as needed.

| Lot Conc. | 99% Rejection | | 95% Rejection | | 90% Rejection | |
|---|---|---|---|---|---|---|
| | Kernels | Approx. Grams | Kernels | Approx. Grams | Kernels | Approx. Grams |
| 0.05 | 9209 | 2709 | 5990 | 1762 | 4605 | 1355 |
| 0.10 | 4603 | 1354 | 2995 | 881 | 2302 | 678 |
| 0.20 | 2301 | 677 | 1497 | 441 | 1151 | 339 |
| 0.30 | 1533 | 451 | 998 | 294 | 767 | 226 |
| 0.40 | 1149 | 338 | 748 | 220 | 575 | 170 |
| 0.50 | 919 | 271 | 598 | 176 | 460 | 136 |

Source: Federal Grain Inspection Service, Practical Application of Sampling for the Detection of Biotech Grains – October 2000.

**Testing Technologies and Protocols**

Testing technologies may be described according to the type of data they provide. Tests are sometimes described as providing data that indicates the presence and/or the amount of GM material in a tested product.

Qualitative tests. Some tests will yield *qualitative* results, in that they are designed primarily to indicate the presence of a GM trait in a sample, but not necessarily the extent to which it is present. A qualitative test will provide a "yes" or "no" answer to the question of whether GM material is present above a certain level of detection. A test that is only qualitative will not tell the user what percentage of the seeds in the sample included genetically engineered material. A qualitative test would be appropriate for use when a given trait is not authorized to be present at any level in a shipment.

Quantitative tests. Other tests may yield *quantitative* results, where they may provide the actual percentage of GM material in the sample. A quantitative test would not only report that GM material was present in a sample, but it would also report the percentage of the material in the

sample that is genetically modified. A quantitative test would be appropriate for use when it is desirable to demonstrate that the GM content is at or below a threshold level as specified in a contractual agreement.

Some GM crops are engineered to have multiple GM traits, such as herbicide tolerance and insect resistance. These are referred to as "stacked" traits. When testing samples of grain for GM presence, detecting the presence of kernels with stacked traits may result in inaccurate reporting of GM material in the sample. When stacked traits are present in a sample, reliable quantitative results can only be achieved by testing single kernels or seeds.

Semi-qualitative tests. Some qualitative tests can be designed to provide a certain degree of "semi-quantitative" information. Semi-quantitative tests can report whether GM material is present above a series of thresholds, such as 0.10 percent, 0.5 percent and 0.9 percent.

**Types of tests.** There are two types of tests most commonly used for testing for the presence of GM material:

- Enzyme-linked Immunosorbent Assay (ELISA) and
- Polymerase Chain Reaction (PCR).

**ELISA Rapid Test Sample Preparation**

1. Select representative sample.
2. Grind the required number of seeds to a fine powder.
3. Add buffering solution to sample. Mix thoroughly.
4. Allow the seed extract to settle for at least 5 minutes.
5. Insert quick-test strip to required level.
6. Let set for required amount of time.
7. Read results visually or with electronic reader.

NOTE: Test manufactures instruction may vary. It is important to follow test instruction precisely to ensure valid test results.

Enzyme-linked Immunosorbent Assay (ELISA). An ELISA test will indicate the presence of a particular protein or enzyme created by a GM plant. ELISA tests may be in the plate form, typically conducted in laboratories, or designed as lateral flow test strips used commonly in field applications. ELISA rapid test strips are simple to conduct and may be done onsite by trained personnel in just a few moments, even while trucks wait to unload. These tests are widely available and relatively inexpensive at about $6 to $20 per test strip. ELISA tests may not be effective in processed livestock feed products where heating may denature proteins targeted by the test. ELISA tests may be qualitative or semi-

quantitative. Some lateral flow test strips are designed with multiple strips attached together as a "comb" to test for stacked traits in a single product.

Polymerase Chain Reaction (PCR). PCR testing is a DNA-based testing technology that identifies a particular piece of genetic material that is unique to a particular GM trait. The testing process mimics *in vivo* replication of the target sequence over time to create a measureable result which may be observed using gel electrophoresis or fluorescent probes. PCR is demonstrably the more powerful and sensitive technology of tests generally conducted for GM material detection. PCR tests are also relatively expensive and may cost several hundred dollars per test. Samples for PCR testing must be sent into a laboratory and testing may take several hours to complete.

PCR testing can also be used to screen for DNA sequences called "promoter" or "terminator" genes commonly used to control the expression of a biotech trait. Such testing may be used to screen for a broad range of GM materials rather than just checking for the presence of a single GM variety.

**Test sensitivity levels**. The ability of a particular test to detect a particular level of GM content in a sample is typically expressed in percent GM material present. This means that for a given number of seeds, a certain percent of them contain GM material. For example, if a report says that a certain sample of seed contained 1% GM material, it means that (on the average) for every 100 seeds tested, one seed contained GM material. This would also mean that the test would have to be capable of detecting the presence of the GM sequence or a protein produced by the GM sequence at this level. Sensitivity levels of rapid test kits range from detecting 1 GM kernel in 100 kernels sampled to detecting 1 GM kernel in 1000 kernels sampled. Sensitive PCR tests can detect at the 0.01 percent level (1 GM kernel in 10,000 kernels).

The testing technology used depends on what features are most valuable or needed for the desired outcome. Speed, cost, accuracy and the type of information provided are factors to consider when users select the type of tests that best suit their needs.

| Comparing ELISA to PCR | |
|---|---|
| **ELISA** | **PCR** |
| Inexpensive | Relatively expensive |
| Results in a matter of minutes | Results may take several hours to days |
| Easily done onsite by trained personnel | Must be conducted in laboratory |
| Not highly sensitive in most cases | Highly sensitive in most cases |
| Limited to a detecting a single GM trait | May detect multiple traits with single test |
| Qualitative and semi-quantitative results | Qualitative and quantitative results |

Table 1 - ELISA-PCR Comparison

**Sampling Locations in the Production and Distribution Chain**

The presence of GM material in an organic crop may be due to:

- Naturally occurring drift of GM pollen carried by wind and insects from neighboring fields.
- Seed impurities occurring when GM pollen drifts into fields and seed is subsequently saved for future planting.
- Planting equipment shared between organic and conventional farming operations.
- Handling equipment such as augers, conveyors, and elevators used to handle both GM and organic crops.
- Grain wagons and trucks that are not adequately cleaned between hauling GM and organic crops.
- Grain bins and drying equipment where residual GM crops may commingle with organic crops.
- Custom harvesting machinery or shared equipment such as combines previously used to harvest a GM crop.[21]

Livestock feed stuffs are relatively minimally processed in comparison to many human foods. Most feed ingredients are simply ground prior to mixing into feed. Some ingredients, such as oils and fats that are added to increase the energy content of feeds, are pressed from oil seeds. Oils do not contain the proteins which would identify the product as GM, so there would be no point in testing oils for GM material content. However, oilseeds may be tested prior to extracting oils to determine GM material content.

Testing seed at point of production. Testing seed at the point of production may be a part of an established certification program or conducted to meet other regulatory requirements for varietal purity. Most testing conducted at the point of production would include seeds produced by commercial organic seed producers or farmers who save seed from their own organic crops. Testing seeds prior to planting can provide a baseline of GM presence prior to other factors being involved.

Testing seed at point of packaging or distribution. Companies that receive and repackage organic seeds must be certified by an NOP-accredited certifying agent. Seeds may be purchased from contract grain and forage seed producers and repacked for distribution. The objective of testing at this point in the distribution chain would be to ensure the quality control of products received and the integrity of the handling process. Therefore, testing may be conducted on in-coming bulk product and out-going packaged product.

Testing purchased seed prior to planting. The usefulness of testing seed prior to planting will depend on the source of the seed and the methods used to handle the seed up to that point. Certified organic seed obtained from a certified organic seed producer will have already been subject to a process review before sale and distribution. However, if seed was obtained from a neighboring organic farm and has not been tested, testing using either PCR or ELISA may be useful in verifying the absence of GM material prior to planting.

Testing saved seed prior to storage. Some farmers will save seed for use in the next season's crop. Clean, weed-free seed may be saved from interior portions of field to avoid contamination from weed seeds and GM drift from nearby crops of the same species. Seed is sometimes cleaned prior to storage to remove foreign material such as chaff, dirt, weed seeds and other foreign material. If seed is cleaned, the cleaning must be done by a certified organic handler or under the organic system plan of a certified operation. Cleaning equipment must be thoroughly cleaned to avoid commingling with foreign material or prohibited substances. If seed is tested for GM presence after cleaning, it would provide information on the GM material content of the crop produced and the seed being saved for the next crop with clear traceability to the source of the seed.

Testing saved seed prior to planting. As with above, testing saved seed for GM material presence can help avoid planting seed containing GM material and a resulting unacceptable crop. However, testing only after storage and prior to planting leaves the possibility that a farmer could incur the cost or inconvenience of storing seed later deemed unacceptable for use in organic production. This option could be used if there are concerns about possible contamination or commingling of previously tested seed during storage.

Testing forage and feed grain crops in the field. Testing feed or forage crops prior to harvest while they are still in the field would provide direct information on the condition of the current crop prior to grazing or harvesting and feeding to livestock. Certifiers or NOP investigators may find this option useful if there are complaints that a crop has been planted using GM seeds or may have been affected by drift. Testing at this point of the production cycle may be useful for non-routine sampling or as part of a multi-layered investigation.

Sampling in-field at harvest. In this instance, grain or oilseed crops are selected and sampled directly from the combine bin or truck in the field. This sampling scenario may be useful when addressing concerns about possible GM drift in a particular area of a field, before hauling crops to markets or investing in cleaning or storage of seed. ELISA quick test strips provide easy onsite testing for a single or small number of GM traits.

Sampling prior to unloading at the elevator. This is a common point of testing of organic livestock feed grains. Since similar types and qualities of grains will be stored together at this point, grain buyers and elevator operators will typically test for a variety of factors before combining the grain with products of similar condition and quality. If organic corn or soybeans are sold into domestic GMO-free or European Union export markets, receiving elevators will commonly perform a quick, qualitative ELISA test for GM presence. Loads that test positive may be rejected or segregated for more definitive testing prior to storage or reclassification.

Sampling at port. Imported or exported grain or oilseeds may be tested for GM presence prior to loading or unloading at the port to verify regulatory quality, phytosanitary or contractual requirements. This testing will not likely provide for trace back to an individual farm.

Sampling grain in storage**.** Grain already in commercial storage may be sampled again prior to further distribution or sale for processing. Sampling conducted at this point does not generally

provide trace back capability because it has already been commingled with grain from other farms. However, it is possible that testing at this step may provide traceback to a group of producers who contributed products to a particular container or shipment.

Sampling at feed mill. Feed mill operators may conduct quick tests of loads of non-GM or organic products using lateral flow strips upon arrival at the mill as a quality control measure and to verify contractual requirements. Rapid test kits are most commonly used for routine screening of this nature. When a rapid test shows a positive result, samples are sometimes sent to a laboratory for confirming quantitative PCR analysis. This testing scenario will not generally provide trace back to the individual farm of origin unless it is a direct shipment from the farm.

Bunk testing. The last possible testing point for testing feed for the presence of GM material would be in the feed bunk at the farm. Since livestock feed stuffs are generally mixed with other feedstuffs prior to placing in the feed bunk for the animal to consume, it would be impractical to conduct GM testing at this point.

**Determining the Need for Guidance - Analysis**

As mentioned earlier, the purpose of this report is to discuss methods used to sample and test organic agricultural products for the presence of GM material and to determine whether GM testing guidance would be valuable to certifying agents in maintaining the integrity of organic products.

A review of the relevant USDA organic regulations revealed that the use of genetic engineering in organic production and handling is an excluded method; not a prohibited substance. In contrast to the maximum levels of pesticide residues provided in the USDA organic regulations, there are no similar regulatory limits for GM material presence. Therefore, when GM testing is conducted and GM materials are detected, the certifying agent needs to determine:

1) whether excluded methods have been used;

2) whether inadequate buffer zones are present to prevent contamination from adjoining land use;

3) whether inadequate procedures were taken to prevent commingling or contamination during handling, or

4) whether reasonable steps were taken to avoid contact with the products of excluded methods.

A review of tests available to detect GM presence in organic livestock feed showed that PCR and ELISA plate and lateral flow strips are the primary tools used in GM material detection. The ease of use and low cost of lateral flow test strips makes these quick tests the tool of choice for on-farm testing or routine screening of loads for GM material. In situations where an accurate, quantitative test conducted by an accredited laboratory is desired, PCR is more likely to be used.

GIPSA and AMS play supportive roles by providing guidance on how to collect representative samples of organic livestock feedstuffs for further testing. GIPSA provides information on testing and sampling at no cost to certifiers or other members of industry on its internet website. AMS provides support and information to certifying agents through the NOP.

A review of testing conducted by the industry reveals that receivers of organic products routinely conduct GM testing for contract verification and internal quality management purposes. Buyers may reject loads that test positive for GM material presence or discount and reclassify them as non-organic and sell them to the conventional market.

An analysis of the livestock feed production and handling process revealed several points along the production and handling continuum where testing may be conducted. Information showed that the more portable ELISA lateral flow test strips may be the more cost-effective and efficient in situations where test results are needed very quickly or for routine screening such as on-farm tests and routine quality control.

Further review of the organic livestock feed production and handling process showed that each time an organic product is shipped or handled it may present a new opportunity for exposure to GM material. Care must be taken to prevent commingling with GM products. Existing guidance in the forms of letters and policy statements already provided by the NOP shows that there has been significant communication of USDA policy regarding the presence of low levels of GM material in certified organic crops. The NOP has been consistent in its policy that as long as an organic crop has been produced in accordance with the NOP regulations, the inadvertent

presence of GM material in an organic crop alone does not render the product ineligible for sale as organic. The USDA provided written guidance in a letter to the industry in 2004 and the NOP reiterated this policy as recently as April 2011. Certifiers may test organic products as part of periodic residue testing or when they suspect the use of excluded methods. Certifiers must issue noncompliance notices to organic operations that fail to take adequate measures to avoid contact with excluded methods or prevent commingling of organic and non-organic GM products. However, certifiers may not take adverse action against a certified organic product that takes reasonable steps to avoid contact with GM material.

**Conclusion**

AMS and other USDA agencies have published guidance for certifying agents on the subject of GM presence in organic crops. Recent amendments to the USDA organic regulations require certifiers to conduct periodic testing of organic crops and products. This requirement may be met by testing for the presence of GM materials. NOP has provided guidance and training to certifying agents on sampling, lab selection criteria and responding to positive residue results. Also, GIPSA provides guidance on effective sampling protocols. The guidance and training provided to certifying agents enables them to identify potential violations. Further guidance beyond what has already been provided by USDA would not address any specific needs at this time.

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